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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,417	07/01/2003	Denis Leclerc	15810-1US PM/MG/al	9472

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EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,417	LECLERC ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 13, 15 and 16, drawn to an immugen carrier complex having an immunopotentiating property, consisting of a viral-like particle (VLP) carrying at least one fusion protein, wherein said VLP is derived from a papaya mosaic virus, classified in class 424, subclass 192.1.

II. Claims 12 and 14, drawn to a method for immunopotentianting an immune response in a mammal consisting of administering a VLP carrying at least one immunogen, wherein the immunogen is fused to a protein of said VLP, classified in class 424, subclass 192.1.

III. Claims 12, 14 and 18, drawn to a method for immunopotentianting an immune response in a mammal consisting of administering a VLP with an antigen, wherein the VLP and antigen are not linked, classified in class 424, subclass 202.1.

IV. Claim 17, drawn to a composition comprising a VLP and an immunogenic protein, classified in class 424, subclass 202.1.

V. Claim 19, drawn to a method of using a papaya mosaic virus as a vaccine, classified in class 435, subclass 235.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using t hat product (MPEP § 806.05(h)). Here, the product of Invention I can be used in a materially different process because Invention I's immunogen carrier complex may be used in a diagnostic assay, or for the isolation of a desired antibody.

Invention II is unrelated to Inventions III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of Invention II involves administering a VLP carrying at least one immunogen that is fused to a protein of said VLP. Inventions III-V are drawn to various product and methods, none of which rely on a VLP comprising a fusion protein. The inventions are therefore not capable of use together. The inventions also have different effects since the VLP particle of Invention II would produce a different biological response than the products and methods of Inventions III-V. This provides the inventions with different effects. For at least these reasons, Invention II is unrelated to Inventions III-V.

Invention III is unrelated to Inventions I and V. Invention III involves administering a VLP with a physically separate antigen. That is, Invention III is drawn to a method of combination therapy. Invention I on the other hand is drawn to a VLP comprising a fusion protein, while Invention V is a method of using a papaya mosaic virus. The combination therapy of Invention III does not rely on either a fusion protein, or a papaya mosaic virus. Thus,

Invention III is not disclosed as capable of being used with Inventions I and V. Invention III also has a different effect than Inventions I and V since its VLP and a physically separate antigen would produce a different immune response than the products of Inventions I and V. The inventions are therefore unrelated.

Invention IV is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the VLP and antigen of Invention IV can be used in a diagnostic assay, or to purify antibodies. Thus, Invention IV can be used in a materially different process than Invention III. For at least these reasons, the inventions are unrelated.

Invention IV is unrelated to Inventions I and V. First, the Inventions are not disclosed as capable of being used together. This is because neither the VLP of Invention I, nor the use of a papaya mosaic virus as an adjuvant (Invention V), involve Invention IV's VLP combination therapy. Second, Invention IV has a materially different use. That is, the VLP and immunogenic protein of Invention IV can be used in a diagnostic assay, or to purify antibodies. For at least these two reasons, the inventions are unrelated.

Invention I is unrelated to Invention V. Invention I, a VLP comprising a fusion protein, has not been disclosed as capable of being used with Invention V's method of using a papaya mosaic virus as an adjuvant. Also, the VLP and fusion protein of Invention I can be used in a materially different process since they can be used in a diagnostic assay, or to purify antibodies. Inventions I and V are therefore unrelated.

An election of Invention I requires an election of one of the following immunopotentiating effects:

i. Adjuvant effect

ii. Capacity to enhance cell-mediated dependent antibody production

iii. Capacity to enhance T-cell dependendent antibody production

iv. Capacity of enhancing the expression of at least one co-stimulator on macrophages

v. Capacity of enhancing the expression of at least one co-stimulator on antigen presenting cells

Restriction between these groups is proper because they are unrelated. Each of the immunopotentiating effects requires a different and distinct protein signal in order to be initiated. Moreover, each of the immunopotentiating effects produces a unique biological and physiological response. For at least these reasons, Groups i-v are unrelated.

An election of Invention I requires a further election of one of the following immunogens:

vi. An allergen

vii. A viral immunogen

viii. A bacterial immunogen

ix. A parasitic immunogen

Restriction between these groups is proper because the listed immunogens are unrelated. This results because each member of the group has a unique physical and chemical structure. The listed immunogens also have different effects in that they each produce a unique, monospecific immune response. This is especially true of Group vi since allergens stimulate the production of IgE and histamines.

An election of Invention IV requires a further election of one of the following immunogenic proteins:

x. A bacterial protein

xi. A viral protein

xii. A parasitic protein

Restriction between these groups is proper for the same reasons as discussed under the restriction of Groups vi through ix.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy M. Brown can be reached on (571) 272-0773. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

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